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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/802,376	03/09/2001	Gary Van Nest	377882001700	8397

25226 7590 05/07/2003

MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER

ZARA, JANE J

ART UNIT PAPER NUMBER

1635

DATE MAILED 05/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File

# Office Action Summary

Application No.

09/802,376

Applicant(s)

Van Nest et al

Examiner

Jane Zara

Art Unit

1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2003
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above, claim(s) 12-55 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 56-66 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some\* c) None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO 892); 4) Interview Summary (PTO 413) Paper No.s \_\_\_\_\_
- 2) Notice of Draftsperson's Patent Drawing Review (PTO 948); 5) Notice of Informal Patent Application (PTO 152);
- 3) ☒ Information Disclosure Statement s: PTO 1449; Paper No.s 5, 7, 11; 6) Other \_\_\_\_\_

File

Application Control Number: 09 802,376

Page 2

Art Unit: 1635

### **DETAILED ACTION**

This Office action is in response to the communication filed February 20, 2003, Paper No. 14.

Claims 1-66 are pending in the instant application.

#### ***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that no distinction exists between the compositions of Group I and the methods of Group II and furthermore that the classifications attributed to Group I (class 435, subclass 23.1) and Group II (514:44) are incorrect. This is not found persuasive because the compositions claims of Group I and methods claims of Group II are patentably distinct and a proper examination of each group requires addressing different and distinct issues, in both searching the prior art and in addressing pertinent issues such as written description and enablement. The composition of Group I can be used for other purposes than that indicated in the methods of Group II. Furthermore, searching both of these patentably distinct groups would place an undue burden on the examiner.

Applicant's representative is correct in pointing the error in classifying Group I as class 435, subclass 23.1, and should properly be classified as class 536, subclass 23.1, which Group is drawn to compositions comprising DNA or RNA fragments, or modified forms thereof. The

Art Unit: 1635

classification attributed to Group II, comprising treatment methods comprising drug, bio-affecting or body treating compositions, including polynucleotides, however, is correct.

Applicants' election of solid phase microcarrier and covalently linked IMP/MC complexes has also been acknowledged. These inventions (not species) have been rejoined with liquid phase microcarriers and non-covalently linked IMP/MC complexes and have been examined on their merits as indicated in the Office action below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 56-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, the metes and bounds of the term "linked to" cannot be determined (is this covalent?). Appropriate clarification is requested.

Art Unit: 1635

In claim 1, lines 4-5, the term "sequence 5'-C,G-3'" is unclear (e.g. does this refer to contiguous sequences with a 5' to 3' orientation, or to non-contiguous sequences?). Appropriate clarification is requested.

In claim 4, lines 1-2, the term "liquid phase carrier" is unclear (e.g. how can a microcarrier defined in the specification as a "particulate composition which is insoluble in water" (page 12 of the specification) be defined as a "liquid phase carrier"?). Appropriate clarification is requested.

In claim 9, line 2, the term "5'-T,C,G-3'" is unclear (e.g. does this refer to contiguous sequences TCG with a 5' to 3' orientation, or non-contiguous sequences?). Appropriate clarification is requested.

Claim 7 is not further limiting than claim 6, from which it depends.

In claim 10, line 2, the term "5'- purine,purine,C,G-pyrimidine,pyrimidine, C,G-3'" is unclear (e.g. does this refer to contiguous sequences with a 5' to 3' orientation, or to non-contiguous sequences?). Appropriate clarification is requested.

In claim 56, line 3, the term "5'-C,G-3'" is unclear (e.g. does this refer to contiguous sequences with a 5' to 3' orientation, or non-contiguous sequences?). Appropriate clarification is requested.

In claim 64, lines 1-2, the term "5'-T,C,G-3'" is unclear (e.g. does this refer to contiguous sequences with a 5' to 3' orientation, or non-contiguous sequences?). Appropriate clarification is requested.

Art Unit: 1635

In claim 65, lines 1-2, the term "5'- purine, purine, C, G, pyrimidine, pyrimidine, C, G-3'" is unclear (e.g. does this refer to contiguous sequences with a 5' to 3' orientation, or to non-contiguous sequences?). Appropriate clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 56-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions comprising immunomodulatory polynucleotide/microcarrier complexes, wherein the immunomodulatory polynucleotide component comprises an immunostimulatory sequence comprising 5' -C, G- 3', or 5'- purine, purine, C, G, pyrimidine, pyrimidine, C, G-3', or 5'-T, C, G-3', as well as kits comprising immunomodulatory polynucleotide/microcarrier complexes with written instructions for their use for immunomodulation in subjects. The specification and claims, however, do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising immunomodulatory polynucleotide components comprising an immunostimulatory sequence comprising 5' -C, G- 3', or 5'- purine-purine-C, G-pyrimidine-pyrimidine-3', or 5'-T, C, G-3'. The

Art Unit: 1635

scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Concise structural features that could distinguish compounds within the genus comprising immunomodulatory polynucleotide components comprising an immunostimulatory sequence comprising 5' -C, G- 3', or 5'- purine-purine-C,G-pyrimidine-pyrimidine-3', or 5'-T,C,G-3' are missing from the disclosure. No adequate written description has been provided for kits containing this broad array of compositions and their use for immunomodulation in any and/or all subjects. The general knowledge and level of skill in the art do not supplement the omitted descriptions because specific, not general guidance is what is needed for this broad genus, as well as for their use in any and/or all subjects for immunomodulation. Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genus, and because the genus is highly variant, the description provided for the broad array of compositions and their use in any and/or all subjects is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the broad genus claimed. Thus, Applicant was not in possession of the claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1635

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sonchra et al.

Sonchra et al teach immunomodulatory polynucleotide microcarrier complexes comprising antigen free, immunostimulatory sequences 5' C-G3', and 5' T-C-G 3', between 5um and 25nm in size, which polynucleotide is not covalently linked to the microcarrier (See especially page 800; tables III and IV on page 801; text on page 802).

Claims 1-7, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al.

Schwartz et al teach immunomodulatory polynucleotide microcarrier complexes comprising an antigen, immunostimulatory sequences 5' -C-G-3', and 5'-T-C-G-3', 5'-purine,purine,C,G,pyrimidine,pyrimidine-3', or 5'-T,C,G-3 or SEQ ID NO: 1, which complexes are or between 5um and 25nm in size, which polynucleotide is covalently or non-covalently linked to the microcarrier, and which microcarrier is a liquid phase or solid phase carrier (See entire document, especially pages 4-6, 12, 16, and table I on page 29; see accompanying sequence alignment data).



Art Unit: 1635

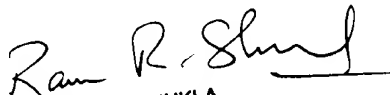
***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

May 5, 2003

  
RAM SHUKLA  
PRIMARY EXAMINER